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| SERIAL NUMBER | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY OR AGENT NO. |
|---------------|-------------|----------------------|-----------------------|
| 07/202,869 | 06/03/88 | HOROSZEWICZ | J 6453-002 |

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EXAMINER
HUTZELL, P.

| ART UNIT | PAPER NUMBER |
|----------|--------------|
| 1806 | 10 |

DATE MAILED: 10/17/91

This is a communication from the examiner in charge of your application
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☒ Responsive to communication filed on 7/1/91 ☒ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), 0 days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- | | |
|---|---|
| 1. <input type="checkbox"/> Notice of References Cited by Examiner, PTO-892. | 2. <input type="checkbox"/> Notice re Patent Drawing, PTO-948. |
| 3. <input type="checkbox"/> Notice of Art Cited by Applicant, PTO-1449. | 4. <input type="checkbox"/> Notice of Informal Patent Application, Form PTO-152 |
| 5. <input type="checkbox"/> Information on How to Effect Drawing Changes, PTO-1474. | 6. <input type="checkbox"/> _____ |

Part II SUMMARY OF ACTION

1. ☒ Claims 1-6, 16-19, 24, 25 and 27-42 are pending in the application.
Of the above, claims 25, 27 and 32-42 are withdrawn from consideration.
2. ☒ Claims 7-15, 20-23 and 26 have been cancelled.
3. ☒ Claims 1 and 24 are allowed.
4. ☒ Claims 16-19 are rejected.
5. ☒ Claims 2-6 and 28-31 are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice re Patent Drawing, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____, has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).
12. ☐ Acknowledgement is made of the claim for priority under U.S.C. 119. The certified copy has ☐ been received ☐ not been received
☐ been filed in parent application, serial no. _____; filed on _____.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

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15. Claims 2-6 are objected to as being substantial duplicates of claim 1. Claims 2-6 recite further characteristics of the 7E11-C5 monoclonal antibody claimed in claim 1, but do not differ in scope from claim 1 since all claims are limited to the 7E11.C5 antibody. Cancellation of claims 2-6 is recommended.

16. Claims 16-19 remain rejected under 35 USC § 112, first paragraph for the reasons set forth in paragraph 20 of the previous office action. Applicant has not demonstrated the reproducible production of antibodies having the exact combination of functional properties recited in claims 16 and 18 using the claimed methods.

17. The rejection of claims 1-3, 10, 11, 20, 28, 29 and 31 under 35 USC § 102(b)/103 over Frankel et al. set forth in paragraph 24 of the previous office action is withdrawn in view of the amendment of the claims.

18. The rejection of claims 1-6, 10-14, 20-23, 28, 29 and 31 under 35 USC § 102(b)/103 over Finstad et al. set forth in paragraph 25 of the previous office action is withdrawn in view of the amendment of the claims.

19. The rejection of claims 1-3, 5, 7-11, 28, 29 and 31 under 35 USC § 102(b)/103 over Webb et al. is withdrawn in view of the amendment of the claims.

20. Claims 16-19 remain rejected under 35 USC § 103 over Webb et al. as set forth in paragraph 26 of the previous office action and over Campbell in view of Frankel et al. or Webb et al. or

Wright et al. as set forth in paragraph 27 of the previous office action.

Applicant maintains that the claims are not rendered obvious over the prior art because there is no evidence of record that anyone had previously utilized LNCaP cells alone to obtain antibodies with the recited specificities.

The claims recite a series of conventional method steps for the production of monoclonal antibodies. Webb et al. teach the use of LNCaP cells in combination with other cell lines as an immunogen for the production of hybridomas which secrete monoclonal antibodies specific for prostate cancer-associated antigens. It would have been obvious to use LNCaP cells alone or in combination with other prostate carcinoma cells as immunogens for the production of monoclonal antibodies specific for prostatic carcinoma cells. Note that the use of the open claim language "comprising" does not exclude the use of additional immunogens in the claimed methods. It would not have been unexpected to obtain antibodies having properties as defined in the claims since antibodies having similar properties were known in the art as shown by Webb et al. and Frankel et al.

Even if the claimed antibodies and hybridomas were distinguished over the prior art of record, the claimed methods for producing and using the monoclonal antibodies are conventional and obvious over the prior art absent a showing of the non-obviousness of applying these conventional methods to the

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claimed monoclonal antibodies. See In re Durden 763F,2d 1406 226 USPQ 359.

Claims 1 and 24 are allowed.

Claims 2-6 are objected to for the reasons described in paragraph 15.

Claims 28-31 are objected to as the claims depend from claim 2, which is objected to.

Claims 16-19 are rejected.

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1806.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a). The practice of automatically extending the shortened statutory period an additional month upon the filing of a timely first response to a final rejection has been discontinued by the Office. See 1021 TMOG 35.

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE

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STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM
THE DATE OF THIS FINAL ACTION.

Any inquiry concerning this communication or earlier
communications from the examiner should be directed to Paula
Hutzell whose telephone number is (703) 308-3533.

Any inquiry of a general nature or relating to the status of
this application should be directed to the Group receptionist
whose telephone number is (703) 308-0196.

PH
Hutzell
October 15, 1991

Esther Kepplinger
ESTHER L. KEPPLINGER
SUPERVISORY PATENT EXAMINER
GROUP ART UNIT 182